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Introduction

Claims 19 and 145-152 are pending in the instant application.

Claims 147 and 148 have been amended herewith. Applicants respectfully assert that said amendments are supported by the specification at least at page 6, lines 29-31.

An amendment to correct inventorship accompanies this paper.

Claims 19 and 145-152 stand rejected under 35 U.S.C. 103(a) over U.S. Patent No. 6,458,811 (the '811 Patent).

Claims 19 and 145-152 stand rejected under the judicially created doctrine of obviousness-type double patenting (JCDOTDP) over claims 1, 7, 14 and 17 of the '811 Patent.

Claims 147, 148, 151 and 152 stand rejected under 35 U.S.C. 112, 1st paragraph.

RemarksObviousness

Claims 19 and 145-152 stand rejected under §103(a) as obvious over the '811 Patent. In their prior response, Applicants provided detailed information as to why the '811 Patent is not available as art under 35 U.S.C. §103 due to the operation of 35 U.S.C. §103(c). In this regard, the Examiner stated,

In order to exclude a 102(e) reference under 35 USC 103(c), Applicant must submit a statement, for example, **that the application and the reference, i.e. Arbuthnot et al., 6,458,811, were at the time the invention was made, owned by or, subject to an obligation of assignment to, the same person.** Assignment records, by themselves (without the required statement by applicant) are not sufficient evidence since assignment records do not show the required "at the time the invention was made."

Emphasis in original.

Although Applicant's believe their prior response was explicit in that regard, in order to expedite prosecution, Applicant's reassert herewith that the invention claimed in the present application and the invention claimed in the '811 Patent, were at the time the present invention was made subject to an obligation of assignment to Eli Lilly and Company.

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JCDOTDP: The '811 Patent

Claims 19 and 145-152 stand rejected under the JCDOTDP over claims 1, 7, 14 and 17 of the '811 Patent. While not necessarily agreeing with the Examiner's assessment of the claims, in order to expedite prosecution, Applicants provide a terminal disclaimer complying with 37 C.F.R. §§ 1.130(b), 1.321(c), and 3.73(b) over U.S. Patent No. 6,458,811. Pursuant to *Quad Environmental Technologies v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991), the filing of this Terminal Disclaimer is not an admission or acquiescence by Applicants to, nor shall act as an estoppel upon the Applicants, on the merits of the rejection. Applicants maintain that said Terminal Disclaimer obviates this rejection of the pending claims.

Enablement

Claims 147, 148, 151 and 152 stand rejected under the enablement prong of 35 U.S.C. § 112, 1st paragraph. The Examiner contends that:

The claims requires the "primary prevention" of breast cancer in postmenopausal women, that is to say, a method of thwarting or warding off breast cancer in post-menopausal women.

Applicants respectfully assert that the Examiner's characterization of the rejected claims is inaccurate and as a result, this rejection is not proper.

Applicants note that these rejected claims all depend from claim 145. Claim 145 recites:

A method for **reducing the likelihood of incurring or developing estrogen-dependent breast cancer** in a post-menopausal woman diagnosed as being in need of such therapy comprising

Emphasis added.

Thus, all of the pending claims, including the rejected claims are directed to **reducing the likelihood of incurring or developing breast cancer**. None of the claims are directed to "prevention" of breast cancer in the sense that the United States Patent and Trademark Office has recently been interpreting this term. Nevertheless, in order to further clarify Applicant's invention, Claims 147 and 148 have been amended herewith to remove the term "de novo." In replacement thereof, claims 147 and 148 now recite "in the first instance."

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Taking claim 147 as an example, written in independent form, claim 147 recites:

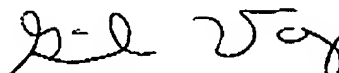
A method for reducing the likelihood of incurring or developing estrogen-dependent breast cancer, wherein said incurrence or development of breast cancer is in the first instance, in a post-menopausal woman diagnosed as being in need of such therapy comprising

Thus, Claim 147 and the other claims rejected for an alleged lack of enablement are directed to reducing the likelihood of incurring or developing estrogen-dependent breast cancer *in the first instance*. Applicants respectfully request favorable reconsideration of this rejection.

Conclusion

Applicants respectfully submit that the pending claims are in condition for allowance.

Respectfully submitted,



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